NOV 4 2002

K022047
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Osborn Medical

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100 West Main
P.O. Box 324
Utica, MN 55979
USA

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1. *Submitter's Name:* Osborn Medical Corporation
2. *Address:* 100 West Main
Utica
Minnesota 55979
3. *Telephone:* 507-932-5028
4. *Contact Person:* Bill Davis
5. *Date Prepared:* June 18, 2002
6. *Registration Number:* 2184046

B. Device

1. *Name:* Phlebotest 2000
2. *Trade Name:* Phlebotest 2000
3. *Common Name:* Plethysmograph
4. *Classification Name:* Plethysmograph
5. *Product Code:* JOM
6. *Class:* II
7. *Regulation Number:* 870.2870

C. Identification of Legally Marketed Devices

1. *Name:* Varitest (Phlebotest)
2. *K Number:* K882547

D. Description of the Device

The PHLEBOTEST 2000 is a system designed for peripheral vascular diagnostic investigations.

The center of the system is a specially developed patient chair, which can be positioned according to the investigation performed. The patient can be in a sitting or laying position, with legs positioned in different angels using the movable heel and foot support. Patient elevation between laying and sitting positions can be carried out in various speeds according to investigational requirements.

All movements are carried out with low-voltage electrical motors and are directed by a remote hand controller. A pneumatic system consisting of a compressor, pressure tank and valve system is integrated in the system.

Different sensors can be attached to the patients for measuring the various examination possibilities. The sensors and pneumatic system are fully integrated and controlled by hardware and software in connection with a PC Windows-based computer.

A number of special developed software programs for various diagnostic tests support the system.

E. Intended Use Statement

- Phlebotest 2000 is a system for peripheral vascular diagnostic investigations.
  - Outflow phethysmography (OP)
  - Passive Drain and Refill (PDR)
  - Exercise Venous Plethysmography (EVP)
  - Triple Test (TTT) Combination of OP, PDR, and EVP
  - Either Strain Gauges or Air Pressure Cuffs

F. Technical Characteristics Summary

The Phlebotest 2000 is substantially equivalent to the Eureka Varitest (Phlebotest) cleared on November 3, 1988.

Osborn Medical Corporation undertook extensive verifications of the software and testing to appropriate standards to verify the Phlebotest's safety and functional outcomes.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 4 2002

Osborn Medical, Inc.
c/o Mr. Bill D. Davis
President
100 West Main
P.O. Box 324
Utica, Minnesota 55979

Re: K022047
Trade Name: Phlebotest 2000
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, Pneumatic, or Photoelectric Plethysmograph
Regulatory Class: Class II (two)
Product Code: JOM
Dated: October 8, 2002
Received: October 9, 2002

Dear Mr. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

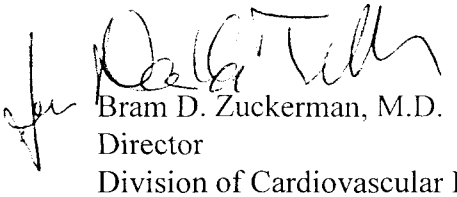
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: *To be determined* K022047

Device Name: Phlebotest 2000

Indications for Use:

- Phlebotest 2000 is a system for peripheral vascular diagnostic investigations.
  - Outflow phethysmography (OP)
  - Passive Drain and Refill (PDR)
  - Exercise Venous Plethysmography (EVP)
  - Triple Test (TTT) Combination of OP, PDR, and EVP
  - Either Strain Gauges or Air Pressure Cuffs
  - Prescription device by a physician

PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR OVER-THE-COUNTER USE ____
(optional Form 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022047